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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/678,454	10/01/2003	William E. Delaney	262.PC2	7810

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EXAMINER	
ALONZO, NORMA LYN	

ART UNIT	PAPER NUMBER
1632	

DATE MAILED: 10/19/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/678,454	DELANEY ET AL.	
	Examiner	Art Unit	
	Norma C Alonzo	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-50 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-50 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 1-50 are pending.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

Set I

I. Claims 1-7 and 10-12, drawn to Duck hepatitis B virus rtA181V or rtA181T, a duck infected with said virus, a vector comprising the nucleic acid encoding hepatitis B virus rtA181V or rtA181T, a host cell transformed with said vector and a method comprising culturing said host cell, classified in class 435, subclass 235.1.

II. Claims 8-9, drawn to Woodchuck hepatitis virus rtA181V or rtA181T, a vector comprising the nucleic acid encoding hepatitis B virus rtA181V or rtA181T, a host cell transformed with said vector and a method comprising culturing said host cell, classified in class 435, subclass 235.1.

III. Claims 13-15, 18, and 26-30, drawn to a reverse transcriptase comprising isolated hepatitis B virus rtA181V or rtA181T and a method for immunotherapy comprising administering to a subject said transcriptase, classified in class 435, subclass 183.

IV. Claims 16-17 and 19, drawn to an antibody capable of specifically binding rtA181V or rtA181T and a method for immunotherapy comprising

administering to a subject said antibody, classified in class 424, subclass 159.1.

V. Claims 20-24 and 45-59, drawn to a method for treatment of HBV or prevention of emergence of rtA181V or rtA181T in a subject undergoing therapy for HBV comprising administering adefovir to a subject infected with HBV, classified in class 514, subclass 44.

VI. Claim 25, drawn to a diagnostic PCR kit for HBV rtA181V or rtA181T comprising primers capable of specifically amplifying an HBV rt sequence containing rtA181V or rtA181T, classified in class 435, subclass 6.

Set II

RAB 10/12/04

VII. Claims ~~26~~ 31-32 and 35-37, drawn to Duck hepatitis B virus sL173F or sL172trunc, a duck infected with said virus, a vector comprising the nucleic acid encoding hepatitis B virus sL173F or sL172trunc, a host cell transformed with said vector and a method comprising culturing said host cell, classified in class 435, subclass 235.1.

VIII. Claims 33-34, drawn to Woodchuck hepatitis virus sL173F or sL172trunc, a vector comprising the nucleic acid encoding hepatitis B virus sL173F or sL172trunc, a host cell transformed with said vector and a method comprising culturing said host cell, classified in class 435, subclass 235.1.

IX. Claims 38-40, and 43, drawn to a hepatitis B virus sAg comprising isolated hepatitis B virus sL173F or sL172trunc and/or sL173F or sL172trunc fused to a heterologous polypeptide, classified in class 424, subclass 185.1.

X. Claims 41-42 and 44, drawn to an antibody capable of specifically binding sL173F or sL172trunc and a method for immunotherapy comprising administering to a subject said antibody, classified in class 424, subclass 159.1.

XI. Claim 50, drawn to a diagnostic PCR kit for HBV sL173F or sL172trunc comprising primers capable of specifically amplifying an HBV rt sequence containing sL173F or sL172trunc, classified in class 435, subclass 6.

The inventions are distinct, each from the other because of the following reasons:

2. The inventions of Group I and II are patentably distinct. Whereas Group I is directed to Duck hepatitis B virus rtA181V or rtA181T, a duck infected with said virus, a vector comprising Duck rtA181V or rtA181T, a host cell transformed with said vector and a method comprising culturing said host cell, Group II is directed to Woodchuck hepatitis virus rtA181V or rtA181T, a Woodchuck infected with said virus, a vector comprising Woodchuck rtA181V or rtA181T, a host cell transformed with said vector and a method comprising culturing said host cell. The inventions are drawn to different a virus and an infected animal of different animal species having distinct physical structure, function and utility. For example, a duck infected with a virus is patentably

distinct from a woodchuck infected with a virus. Therefore, because the inventions are different, each from the other, they are patentably distinct and will require a separate search in the patent and non-patent literature.

3. The inventions of Group I and III are patentably distinct. Whereas Group I is directed to Duck hepatitis B virus rtA181V or rtA181T, a duck infected with said virus, a vector comprising Duck rtA181V or rtA181T, a host cell transformed with said vector and a method comprising culturing said host cell, Group III is directed to a reverse transcriptase comprising isolated rtA181V or rtA181T. The inventions of the two groups are drawn to compositions having different physical structure, function and utility. For example, a virus and a duck infected with said virus is patentably distinct from an enzyme. Therefore, because the inventions are different, each from the other, they are patentably distinct and will require a separate search in the patent and non-patent literature.

4. The inventions of Group I and IV are patentably distinct. Whereas Group I is directed to Duck hepatitis B virus rtA181V or rtA181T, a duck infected with said virus, a vector comprising Duck rtA181V or rtA181T, a host cell transformed with said vector and a method comprising culturing said host cell, Group IV is directed to an antibody capable of specifically binding to rtA181V or rtA181T. The inventions of the two groups are drawn to compositions having different physical structure, function and utility. For example, a duck has a different physical structure, function and utility from an antibody.

Therefore, because the inventions are different, each from the other, they are patentably distinct and will require a separate search in the patent and non-patent literature.

5. The inventions of Group I and V are patentably distinct. Whereas Group I is directed to Duck hepatitis B virus rtA181V or rtA181T, a duck infected with said virus, a vector comprising Duck rtA181V or rtA181T, a host cell transformed with said vector and a method comprising culturing said host cell, Group V is directed to a method for treatment of HBV. The inventions are therefore drawn to different compositions having distinct physical structure, function and utility. For example, a duck infected with a virus has a different function and utility from a method of treatment. Therefore, because the inventions are different, each from the other, they are patentably distinct and will require a separate search in the patent and non-patent literature.

6. The inventions of Group I and VI are patentably distinct. Whereas Group I is directed to Duck hepatitis B virus rtA181V or rtA181T, a duck infected with said virus, a vector comprising Duck rtA181V or rtA181T, a host cell transformed with said vector and a method comprising culturing said host cell, Group VI is directed to a diagnostic PCR kit for HBV rtA181V or rtA181T comprising primers capable of specifically amplifying an HBV rt sequence containing rtA181V or rtA181T. The inventions of the two groups are drawn to compositions having different physical structure, function and utility. For example, a duck has a different physical structure, function and utility from a

diagnostic PCR kit. Therefore, because the inventions are different, each from the other, they are patentably distinct and will require a separate search in the patent and non-patent literature.

7. The inventions of Group VII and VIII are patentably distinct. Whereas Group VII is directed to Duck hepatitis B virus sL173F or sL172trunc, a duck infected with said virus, a vector comprising Duck sL173F or sL172trunc, a host cell transformed with said vector and a method comprising culturing said host cell, Group VIII is directed to Woodchuck hepatitis virus sL173F or sL172trunc, a woodchuck infected with said virus, a vector comprising Duck sL173F or sL172trunc, a host cell transformed with said vector and a method comprising culturing said host cell. The inventions are drawn to different a virus and an infected animal of different animal species having distinct physical structure, function and utility. For example, a duck infected with a virus is patentably distinct from a woodchuck infected with a virus. Therefore, because the inventions are different, each from the other, they are patentably distinct and will require a separate search in the patent and non-patent literature.

8. The inventions of Group VII and IX are patentably distinct. Whereas Group VII is directed to Duck hepatitis B virus sL173F or sL172trunc, a duck infected with said virus, a vector comprising Duck sL173F or sL172trunc, a host cell transformed with said vector and a method comprising culturing said host cell, Group IX is directed to a surface antigen (sAg) comprising isolated sL173F or sL172trunc fused to a polypeptide.

The inventions of the two groups are drawn to compositions having different physical structure, function and utility. For example, a virus and a duck infected with said virus is patentably distinct from a surface antigen. Therefore, because the inventions are different, each from the other, they are patentably distinct and will require a separate search in the patent and non-patent literature.

9. The inventions of Group VII and X are patentably distinct. Whereas Group VII is directed to Duck hepatitis B virus sL173F or sL172trunc, a duck infected with said virus, a vector comprising Duck sL173F or sL172trunc, a host cell transformed with said vector and a method comprising culturing said host cell, Group X is directed to an antibody capable of specifically binding to sL173F or sL172trunc. The inventions of the two groups are drawn to compositions having different physical structure, function and utility. For example, a duck has a different physical structure, function and utility from an antibody. Therefore, because the inventions are different, each from the other, they are patentably distinct and will require a separate search in the patent and non-patent literature.

10. The inventions of Group VII and XI are patentably distinct. Whereas Group VII is directed to Duck hepatitis B virus sL173F or sL172trunc, a duck infected with said virus, a vector comprising Duck sL173F or sL172trunc, a host cell transformed with said vector and a method comprising culturing said host cell, Group XII is directed to a diagnostic PCR kit for sL173F or sL172trunc comprising primers capable of specifically

amplifying an HBV rt sequence containing sL173F or sL172trunc. The inventions of the two groups are drawn to compositions having different physical structure, function and utility. For example, a duck has a different physical structure, function and utility from a diagnostic PCR kit. Therefore, because the inventions are different, each from the other, they are patentably distinct and will require a separate search in the patent and non-patent literature.

11. The inventions of Set I, groups I-VI, are patentably distinct from the inventions of Set II, groups VII-XII. Whereas the inventions of Set I are drawn to compositions and methods relating to virus rtA181V or rt181T, the inventions of Set II are drawn to compositions and methods relating to virus sL173F or sL172trunc. The inventions of the two sets are drawn to compositions having different physical structure, function and utility. For example, a duck infected with the rtA181V reverse transcriptase mutant virus would have a different utility and function from a duck infected with the sL173F surface antigen mutant virus. Therefore, because the inventions are different, each from the other, they are patentably distinct and will require a separate search in the patent and non-patent literature.

12. Claims 22 and 47 are generic to a plurality of disclosed patentably distinct species comprising entecavir, L-dT, MCC-478, FTC, L-dC, L-FMAU, L-Fd4C, Lamivudine and tenofovir.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Claims that are generic are indicated as above.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanies by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP §809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

13. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject

matter, and because each invention requires a separate, non-coextensive search, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Norma C Alonzo whose telephone number is 571-272-2910. The examiner can normally be reached on 8-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on 571-272-0804. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

NCA

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PRIMARY EXAMINER